REMARKS

This Response is to the Office Action mailed May 1, 2003. Claims 1 to 35, 38 to 73 and 95 to 115 were pending previously in this application. Claims 36, 37 and 74 to 94 were previously withdrawn from consideration. Claims 1, 16, 25, 29, 44 and 99 have been amended herein. The specification has also been amended in certain places for grammatical reasons. No new matter has been introduced by way of any of the amendments.

In the Office Action, Claims 1, 3 to 35, 38 to 42, 44 to 48, 51 to 58, 62 to 66, 68 to 71, 73, 95 to 97, 99 to 101, 103 to 108, 111 to 113 and 115 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,527,274 to Zakko ("*Zakko*"). Claims 43, 72, 98 and 114 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,543,087 to Sommercorn et al. ("*Sommercorn*"). Claim 2 was rejected under 35 U.S.C. § 103(a) as being obvious in view of *Zakko* and U.S. Patent No. 5,057,075 to Moncrief et al. ("*Moncrief*").

A previous response to the Office Action of February 14, 2002, stated aptly Applicants' position that the present invention is patentable over the main reference *Zakko*. Each of the points and arguments made therein is therefore incorporated herein by reference. Briefly summarizing the distinction between Applicants' invention and that of *Zakko*, Applicants again emphasize that the catheters of the present invention are intended to be implanted in a patient's peritoneal cavity to perform peritoneal dialysis.

The catheters of the present invention enhance peritoneal dialysis therapy by delivering fresh dialysis solution into the peritoneal cavity at a location separate from the location at which the catheter removes spent dialysis from the cavity. In that manner, the dialysis solution contacts or washes across a relatively large surface area of the peritoneal membrane before the solution exits the catheter. The solution travels through the peritoneal cavity and reenters the catheter at a location of the cavity distant from or opposite from the location that the fluid left the catheter. Fig. 2 of the application illustrates the above advantage. In that figure, the fluid exits the catheter at the top U-shaped portion thereof. The solution reenters the catheter at the lower end of the peritoneal cavity through the coiled end of the catheter.

Zakko on the other hand pertains to a catheter for chemical contact dissolution of gallstones or removing obstructions other than gallstones from organs or body cavities. The *Zakko* catheter is intended to deliver fluid solvents to an obstruction to dissolve that obstruction and then aspirate the fluid solvents. Because the *Zakko* catheter is designed for chemical contact dissolution of gallstones, the catheter has infusion and aspiration ports that are close together and positioned at the distal end of the catheter.

Applicants' catheters are distinguished from *Zakko* because Applicants' catheters space apart the inflow and outflow apertures to create a ranging flow across the peritoneal cavity, whereas *Zakko* spaces the inflow and outflow apertures close together for localized contact. The present catheters are different structurally from the *Zakko* catheter. Moreover, the *Sommercorn* reference does not cure the deficiencies of *Zakko*. The inflow and outflow apertures of *Sommercorn* are spaced together as close or closer than the holes of *Zakko*, as illustrated by Fig. 1 of *Sommercorn*. Further still, *Moncrief* is cited merely to teach the implant cuffs of Claim 2. *Moncrief* does not cure the above-described deficiencies of *Zakko* and *Sommercorn*.

Applicants have amended certain of the claims to clarify the distinctions between the catheters of the present invention and that of *Zakko*. Other claims as originally written or previously added are already sufficiently distinguished over *Zakko* and *Sommercorn*. Those claims do not need to be amended.

Referring now specifically to the claims, Claim 1 has been amended to clarify that a second lumen port in the implantable portion of the catheter is spaced away from a curved segment, wherein a first lumen port is located on the curved segment. Fig. 1 illustrates the clarified distinction. Fig. 1 includes fluid openings or ports 56 and 76. Fluid openings 56 are placed on a curved portion of the catheter. The fluid openings 76 are placed on a portion of the catheter that is spaced away from the curved segment defining fluid openings 56.

Applicants submit that the clarification in Claim 1 distinguishes that claim over *Zakko*. Figs. 4 and 5 of *Zakko* show that the infusion apertures 60 are placed on a curved portion of the *Zakko* catheter. The aspiration apertures 62, however, are placed along the same curved portion as the infusion apertures 60, which is shown clearly in Figs. 4 and 5. Therefore, the aspiration apertures are not spaced apart from the curved

section of the *Zakko* catheter upon which infusion ports 60 are defined. Accordingly, Applicants submit that Claim 1 defines a structural and advantageous distinction over *Zakko*. *Sommercorn* does not show a curved portion and therefore does not remedy the deficiencies of *Zakko* to teach Claim 1 as presently presented. Applicants therefore respectfully submit that Claim 1 and Claims 2 to 15 that depend therefrom are each patentably distinguished over *Zakko*.

Claim 16 has also been amended and clarifies that the patient inflow section is located closer to a position on the connection section that is suitable for attachment to a patient's body than to the patient outflow section. Again, Fig. 1 of the application helps to explain the above clarification. On that figure, the patient inflow section is marked by reference numeral 18. The connection section is marked by reference numeral 16. The patient outflow section is marked by reference numeral 22. Claim 16 therefore clarifies that the patient inflow section 18 is located closer to a point on the connection section 16 that is attached to the patient, i.e., the section in and around cuffs 46 and 48 (attachment shown in Fig. 2), than the inflow section 18 is to the patient outflow section 22.

The above-described clarification distinguishes Claim 16 over *Zakko*. Given the fact that the *Zakko* catheter needs to reach the patient's gallbladder as illustrated in Fig. 11 of that patent, it is clear for example viewing Fig. 4 that the catheter would be attached to the patient at some point closer to the external end of the catheter, so that the infusion openings 60 of *Zakko* are not located closer to that attachment point than are the infusion openings 60 located to the aspiration ports 62. There is no way *Zakko* can meet Claim 16. To do so, infusion openings 60 would need to be located much closer to the external end of the catheter as opposed to being located at virtually the distal end of catheter as shown in Figs. 4 and 5. Column 17 of *Zakko* confirms that point the different holes need to be close together:

> "At least one aspiration opening is located proximal to all infusion openings, preferably being located at the entry point of the catheter into the gallbladder when the catheter is in position for operation. With this configuration, aspiration takes place nearest the insertion point of the catheter into the gallbladder. Any leakage of solvent from the gallbladder through the entry point of the catheter is therefore immediately aspirated and does not damage the surround tissues.

In sum, *Zakko* specifically teaches placing the different apertures close together. Claim 16 on the other hand specifies that inflow apertures are located closer to a portion of the catheter attached to the body than to the patient outflow section, i.e., the section containing the outflow apertures. Applicants respectfully submit that the above-described distinction is a structural difference, is advantageous versus and is therefore and patentable over *Zakko*. Accordingly, Applicants submit that Claim 16 and Claims 17 to 24 that depend therefrom are each currently in condition for allowance.

Claim 25 has been clarified to state that the second and forth fluid openings are in an implantable portion of the catheter and are spaced apart significantly from each other. The word "significantly" is used in the Summary of the Invention to describe the relative spacing between the inflow and outflow locations of the catheter. Moreover, Applicants submit that that term is sufficiently defined by the specification and drawings. Importantly, the openings of *Zakko* and *Sommercorn* do not appear to be spaced apart significantly from each other when compared to the description and drawings of the present invention. The above quoted passage of *Zakko* also expressly contradicts an assertion that the holes of *Zakko* are spaced apart significantly. Accordingly, Applicants submit that the above structural distinction patentably distinguishes Claim 25 and Claims 26 to 28 that depend therefrom over *Zakko*.

Claim 29 has been clarified to state that the separation section extends from the patient inflow section at a junction located closer to an attachment portion than to implanted end of the catheter. Similar to Claim 16 and viewing Fig. 1, Claim 29 clarifies that the separation section 20 extends from a junction 28 that is located closer to an attachment portion of the catheter, e.g., between cuffs 46 and 48, than to an implanted end of the catheter, e.g., end 32 in Fig. 1.

The separation section is located between the different sets of apertures. That analogous section in Figs. 4 and 5 of *Zakko* is clearly located closer to distal end 50 of the *Zakko* catheter than to a portion of the catheter which would be attached to the patient. That structural difference is patentable over *Zakko*. *Sommercorn* does not remedy that deficiency. Accordingly, Applicants respectfully submit that Claim 29 and Claims 30 to 32 that depend therefrom are patentably distinguished over *Zakko*.

Claim 33 has been clarified to state that a fluid port of a non-linear section of the catheter faces away from a distal end section when the catheter is implanted in a patient. Fig. 1 again illustrates the clarification made to Claim 33. The fluid openings 56 face away from the patient outflow section 22. The fluid openings, therefore, direct dialysate up and away from the return ports 76. Such arrangement is advantageous because it encourages maximum coverage of the dialysate against the peritoneal wall. *Zakko* does not disclose such a feature. Indeed, the ports 60 and 62 of *Zakko* are shown oriented slightly inward towards each other. Again, the purpose of *Zakko* is to position the aspiration holes 62 close to the infusion holes 60. Facing the *Zakko* holes away from each other would defeat the stated purpose of *Zakko*. Accordingly, Applicants respectfully submit that the structural differences between Claim 33 and *Zakko* are patentable. Therefore, Claims 34 and 35 that depend from Claim 33 are likewise in condition for allowance.

Applicants believe that for different reasons many of the previously added claims are patentable over *Zakko* and *Sommercorn* without amendment. For example, Claims 38, 62, 69, 95 and 110 each include limitations specifying that the catheter is positioned and arranged when in use in a peritoneal cavity so that fluid flows out of the first lumen in an upper area of the cavity and into the lumen in a lower area of the cavity. Certain of those claims, such as Claims 62 and 110, are more broadly written to specify that the different openings are at generally opposite portions of the peritoneal cavity. In either case, *Zakko* and *Sommercorn* fail to teach, alone or in combination, those elements. Both *Zakko* and *Sommercorn* expressly show different sets of holes that are spaced closely together. *Zakko* states that such arrangement is desirable for that catheter. *Sommercorn* does not appear to specifically state why the holes should be spaced closely together, however, that references only discloses the holes spaced closely together and provides no hint that spacing such holes farther apart is desirable.

Viewing the catheters of *Zakko* and *Sommercorn* along with Fig. 2 of Applicants' Specification, it becomes clear that the *Zakko* and *Sommercorn* catheters would not perform the function of infusing and recapturing dialysate into a patient's peritoneal cavity in the advantageous way described by Applicants. Using the *Zakko* and *Sommercorn* catheters would not enable dialysate to be infused at one end of the

cavity and recaptured at an opposite end. Stated simply, the catheters of Claims 38, 62, 69, 95 and 110 are structurally different than those of *Zakko* and *Sommercorn.* Those structural differences are taught repeatedly in Applicants' Specification to provide an advantageous peritoneal therapy. Those advantages and that therapy were not contemplated by *Zakko* and *Sommercorn.* Thus, one skilled in the art viewing *Zakko* and *Sommercorn* would not likely glean Applicants' invention from their disclosures.

The structural differences between Applicants' catheter and those of *Zakko* and *Sommercorn* as well as the lack of any suggestion or motivation in *Zakko* and *Sommercorn* to produce Applicants' invention both dictate that Claims 38, 62, 69, 95 and 110 are patentably distinguished as originally filed over *Zakko* and *Sommercorn.* Accordingly, Claims 39 to 43, 63 to 68, 70 to 73, 96 to 98, and 111 to 115 that depend respectively therefrom are additionally patentable. Further, the patentability of Claims 38, 62, 69, 95 and 110 renders moot the rejection of Claims 43, 72, 98 and 114 over *Sommercorn.*

Claims 53 and 105 are also patentably distinct as originally presented. Both those claims include an upper preformed, non-linear portion of a catheter that connects fluidly to a connection having a fluid opening and a lower portion fluidly connected to and extending downward from the upper non-linear portion, wherein the lower portion also has a fluid opening. Stated more simply, the catheters of Claims 53 and 105 are preformed at a middle portion thereof. *Zakko* on the other hand states at column 18, line 9 that its catheter is curved at its distal end and is shown in Fig. 7 to have a pigtail shaped end. There is no disclosure in *Zakko* that teaches or suggests a catheter that is preformed at a middle portion. *Sommercorn* shows a straight catheter and does not cure the deficiencies of *Zakko.* Applicants respectfully submit that Claims 53 and 105 provide structural differences over the *Zakko* reference. Accordingly, Claims 53 and 105 and Claims 54 to 61 and 106 to 109 that depend respectively therefrom are each patentably distinct and in condition for allowance.

Claims 44 and 99 have both been amended to provide a similar distinction over *Zakko* as described above in connection with Claims 53 and 105. Both Claims 44 and 99 originally included a patient inflow portion having a preformed, non-linear shape. The amendments to Claims 44 and 99 clarify that the outflow portion is spaced closer

to the distal end than is the patient inflow portion. Those amendments therefore clarify that a section of catheter exists after the preformed bend towards the distal end of the catheter. Such clarifications distinguish those claims over *Zakko*, which requires that the distal end be the preformed or coiled portion. Accordingly, Applicants submit that the structural differences between Claims 44 and 95 render those claims as well as Claims 45 to 52 and 100 to 104 that depend therefrom patentably distinct over *Zakko*. Again, *Sommercorn* does not have a curved shape and does not remedy the deficiencies of *Zakko*.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in a condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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